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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,915	03/19/2004	Lucian V. Di Pietro	A-846	9533

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AMGEN INC.
U.S. Patent Operations/JWB
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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,915	Applicant(s) DI PIETRO ET AL.	
	Examiner REBECCA L. ANDERSON	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-22, 24-31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) 22, 26-29, 39, 41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 is/are rejected.
- 7) ☒ Claim(s) 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5, 8-22, 24-31 and 33-50 are currently pending in the instant application. Claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 are objected to as containing non-elected subject matter and rejected.

Response to Amendment

Applicants' amendment filed 11 January 2008 and Applicants' arguments filed 30 July 2007 have been considered and entered into the instant application.

In regards to the restriction requirement, Applicants' argue that the examiner has failed to set forth a clear intelligible "scope of the invention" that would allow Applicants to submit a reasoned response that could thoroughly address all points raised in the office action; that the Examiner's self-determined "scope of the independent invention" is overly narrow, and examination of a significantly enlarged scope would not seriously burden the Examiner and that MPEP 803.02 mandates that the scope of examination be expanded in some fashion because the examination of the initial scope uncovered no prior art raising issues of unpatentability; and that the office action faults Applicants for not previously providing any rebuttal arguments to the substance of the new restriction requirement.

Applicant argues that the first aspect of unclarity is raised by the Examiner limiting the compounds to the formula III which is only first seen in claim 45, which suggests that the Examiner might be intending to require Applicants to withdrawn the subject matter of claims 1-44 in their entirety. This argument is not persuasive as claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43 include subject matter within the

elected invention for search and examination, therefore, Applicants are not required to withdraw the subject matter of these claims in their entirety. The examiner did not indicate claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43 were withdrawn claims. Applicants may amend claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43 to include only the subject matter as found in the elected invention for search and examination using any of formula I, II and III as long as the subject matter corresponds to the elected invention for search and examination, for example, Applicants' have partially amended claim 1 to subject matter as found in the elected invention for search and examination, see for example wherein ring A has been amended to be phenyl, Y2 is O and Y1 is N.

Applicant argues that the second aspect of unclarity is the initial language employed by the Restriction discussing R1", R1 and R1' which is confusing. The examiner apologizes for the incorrect inclusion of R1", R1 and R1' which was inappropriately pasted into the action. The elected invention for search and examination is provided below for clarity.

Applicant argues that the third aspect of unclarity is that the Office action as well as From PTOL-326 indicates that claims 22, 26-29, 39, 41 and 42 are withdrawn claims, however, the independent claims on which all of these withdrawn claims depend have not been withdrawn. This argument is not persuasive as claims 22, 26-29, 39, 41 and 42, while being dependent upon a claim which is not withdrawn, are drawn solely to non-elected subject matter, i.e. these claims do not fall within the elected invention for search and examination as their limitations are outside of the elected invention for search and examination. Therefore, claims 22, 26-29, 39, 41 and 42 are properly

withdrawn from consideration as being for non-elected subject matter. Claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 have not been withdrawn as they include subject matter within the elected invention for search and examination.

Applicants argue that the restriction requirement is overly narrow and that the Examiner has failed to support the basis for the narrow restriction requirement and has failed to explain why any withdrawn subject matter is allegedly patentably distinct over the examined subject matter. This argument is not persuasive as the examiner has provided support for the restriction requirement, see pages 3 and 4 of the previous office action which states that the non elected subject matter differs materially in structure and composition from the compounds of the elected invention and provides non-elected variables and their classification that supports the recognized chemical diversity of the compounds by the US classification system. These non-elected variables would provide compounds which would be classified in difference classes or subclasses of the US classification system which shows that they differ materially in structure and composition.

Applicants argue that an examination of a claim scope limited to a central benzoxazole core would not seriously burden the Examiner. This argument is not persuasive as the elected invention for search and examination is independent and distinct from the non-elected subject matter because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. The elected invention and the non-elected subject matter are directed to art recognized divergent subject matter which require different searching. Moreover, the

examiner must perform a commercial database search on the subject matter in addition to a paper search, which is quite burdensome to the examiner.

Applicants argue that the procedure outlined in MPEP 803.02 mandates that the scope of examination be expanded in some fashion. This argument is not persuasive as the restriction requirement was made under 35 USC 121. 35 USC 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. So, here we have claims, which involve more than one independent or distinct inventions. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention. The issue here is one of restriction. 35 USC 121 gives the Commissioner the authority to restrict to one invention those applications which contain two or more inventions, I.e. limit the examination of an application to a single invention. Thus, the requirement to restrict in this application is predicated on the fact that the elected subject matter taken as a whole and the non-elected subject matter taken as a whole are so different in structure and element as to be patentably distinct, I.e. a reference which anticipated but one group of compounds would not even render obvious the other group. Accordingly, restriction as has been presented in this application is proper.

Additionally, note that the elected species has been examined fully and additionally, an expanded search up to the elected invention for search and examination has determined that the claims as presented are not allowable (see the following 35 USC 112 2nd paragraph rejection and the provisional double-patenting rejection).

Lastly, Applicants argue that the Examiner faults Applicants for failing to respond to a position that had never before been raised. This argument is not persuasive as the Examiner's position has been previously raised, see pages 3-4 of the restriction requirement which state that "the Office will review claims and disclosure to determine the scope of the independent invention encompassing the elected compound..." and that "should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case."

As the restriction requirement is considered proper, the objection to claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 as containing non-elected subject matter is maintained.

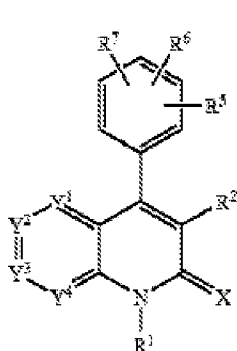
Applicants' amendment to claims 45 and 50 have overcome the objection to these claims as the amendment to claim 45 has overcome the informalities and the amendment to claim 50 has overcome the improper form.

Applicants' amendment has overcome the 35 USC 112 2nd paragraph rejection of the claims as being indefinite for the term "derivative".

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Applicants' amendment has overcome the 35 USC 112 2nd paragraph rejection of claim 45 by deleting the reference to R4.

In regards to the 35 USC 112 2nd paragraph rejection of claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 for the variable R2, Applicants' argue that one of ordinary skill in the art would understand that the variable R2 is intended to define one or more optional substituents that may be present at any location on the central fused phenyl ring. This argument is not persuasive as the formula presented in the claims only include one R2 variably attached. There is no indication that there is more than one R2 on the formula presented in the claim. US Patent No. 7,326,788 discloses the formula:



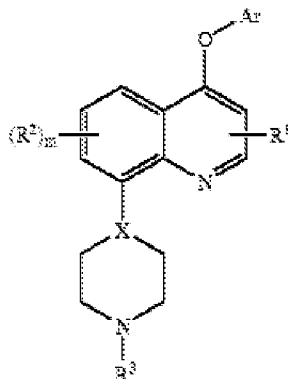
(II)

wherein:

R⁵, R⁶ and R⁷ are independently

—C₁₋₆ alkyl, —C₂₋₆ alkenyl, amino, aminoalkyl, heteroaryl, halogen, meta-hydroxy, para-hydroxy, meta-methoxy, para-methoxy, —C₂₋₅ alkoxy, —CF₃, aryl, aralkyl, heteroaralkyl, aryloxy, arylalkoxy, —OCF₃, —OCO-alkyl, —COR_a, —CN, —COOR_a, —CON-R_aR_b, —N(R_a)COR_b, —NO₂, —SR_a, —SO₂R_a, —NR_aSO₂R_b, —SO₃R_a or —SO₂NR_aR_b;

, and US Patent No. 7,307,089



discloses the formula:

wherein:

m is an integer from 0 to 3;

X is —CH— or —N—;

Ar is optionally substituted aryl or optionally substituted heteroaryl;

R¹ is hydrogen, halo, alkyl, haloalkyl, heteroalkyl, alkoxy, cyano, —S(O)_s—R^c, —C(=O)—NR^cR^d, —SO₂—NR^cR^d, —N(R^c)—C(=O)—R^d, or —C(=O)—R^c;

each R² halo, alkyl, haloalkyl, heteroalkyl, alkoxy, cyano, —S(O)_s—R^c, —C(=O)—NR^cR^d, —SO₂—NR^cR^d, —N(R^c)—C(=O)—R^d, or —C(=O)—R^c;

. These patents provide examples which

show that one of ordinary skill in the art would understand that the variable attachment of multiple substituents can be shown by multiple R values (see R5, R6, and R7 shown above) or parenthesis of the R value with an indication of how many times the variable can be present (see (R2)m shown above) and that one single variable attachment can be shown with one R value (see R1 shown above). The rejection is therefore maintained.

Applicants' amendment and arguments have overcome the 35 USC 112 2nd paragraph rejection of the claims for the terms "comprise" and "contain".

In regards to the double-patenting rejection, as the rejection is provisional, Applicants' defer responding to the rejection until such a time as any claim(s) actually

issue from Application Serial No. 11/042,398. As the provisional rejection is still considered proper, the provisional rejection is maintained.

Election/Restrictions

Based upon Applicant's election of Group I and the further election of example 259, as stated in the previous office action, **the elected invention for search and examination is:**

The products of the formula (III) wherein:

W is NH;

X is O;

R is selected from a) or d);

R1a is substituted or unsubstituted 4-quinolyl and is optionally substituted as found in claim 45;

R2 is one or more substituents independently selected from H, halo, optionally substituted cycloalkyl, optionally substituted phenyl, cyano, alkylaminoalkoxy, nitro, and lower alkyl substituted with R6;

R3 is as found in claim 45; and

R6 is one or more substituents independently selected from H, halo, optionally substituted cycloalkyl, optionally substituted phenyl, cyano, alkylaminoalkoxy and nitro.

As the restriction presented is considered proper, the restriction is FINAL.

Maintained Claim Objections

Claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 are objected to as containing non-elected subject matter. Claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and

43-50 presented drawn solely to the elected invention as identified supra as the elected invention for search and examination would overcome this objection.

New Claim Objections

Claim 50 is objected to because of the following informalities: Specifically, claim 50 is dependent upon a multitude of cancelled claims as claims 6, 7, 23 and 32 are cancelled. Appropriate correction is required.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8-21, 24, 25, 30, 31, 33-38, 40 and 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims contain one variable R2 which is variably attached to the compounds, however, the claims also state wherein "R2 is one or more substituents...". This renders the claims indefinite as it is unclear how one variable R2 is also more than one substituent and it is also unclear how many "more" R2 variables are present.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 8, 9, 11-17, 19-21, 24, 30, 31, 33, 34, 36-38, 40, 43, 45, 46, and 48-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 42 of copending Application No. 11/042,398. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 22 claims 5-(6,7-bis(methoxy)-4-quinolinyl)oxy)-N-(4-chlorophenyl)-1,3-benzoxazole-2-amine which anticipates

applicants' claimed invention. Conflicting claim 42 is a pharmaceutical composition. The difference between the conflicting claims and applicants' elected invention is that the conflicting claims anticipate applicants' claimed invention. Therefore, the claims are provisionally rejected as obvious type double patenting since the conflicting claim 22 is claiming a species that is within applicants' claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

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14 April 2008